Remarks

Favorable reconsideration of this application is respectfully requested. Claims 15, 16, and 27 are amended and supported for example, at Table 1 and the description of the reported results. No new matter has been added. Claims 15, 16, and 27 are pending.

Claim Rejections under 35 U.S.C. § 103

Claims 15-16 and 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hidaka et al. (US Patent 5,972,976) in view of Goodman and Gilman (1996) as made of record in Paper No. 20091218 and as follows. Applicants respectfully request reconsideration of the rejection.

The rejection states at page 4 that Hidaka discloses the claimed compound (E)-4-[2-[2-[N-acetyl-N-[(p-methoxyphenyl)sulfonyl]amino]phenyl]ethenyl]pyridine 1-oxide, Based on Goodman and Gilman which teaches that anticancer drugs may be combined, the rejection goes on to conclude that one of skill in the art would have been motivated to combine a known anticancer drug with the compound of Hidaka. Applicants respectfully submit that this conclusion is unreasonable and is one that results from far too much speculation. Goodman and Gilman only generally mentions that drugs are more effective in combination. However, there is no particular guidance in Goodman and Gilman as to particular mechanisms, biochemical interactions, or other factors, which one might target, so as to lead one of skill in the art to combine the compounds as required by claim 27. Rather, the reference only generally acknowledges that a number of factors must be taken into account when developing regimens for clinical use. And given the vast number of compounds that one might attempt to combine, there is no reason that one of skill in the art would have arrived at selecting the claimed combination of compounds required by claim 27, much less have expected success in doing so. Thus, claim 27 does not follow from the references cited.

Furthermore, claim 27 recites that the method comprises administering a therapeutically synergistic inhibitory effective amount of (E)-4-[2-[2-[N-acetyl-N-[(p-methoxyphenyl)sulfonyl]amino]phenyl]ethenyl]pyridine 1-oxide in combination with cisplatin. That is, method claim 27 provides a combination therapy of two specific

compounds. The prior art neither discloses nor teaches such a method. Applicants' respectfully submit that requiring the claim to include a specific dosage amount is not reasonable. Applicants have demonstrated that claim 27 has an advantage over the prior art based alone on the combination therapy of (E)-4-[2-[2-[N-acetyl-N-[(p-methoxyphenyl)sulfonyl]amino]phenyl]ethenyl]pyridine 1-oxide) (i.e. compound 2) with cisplatin. For instance, Applicants report in their Example 2 on the antitumor effect of compound 2 on murine monocytic leukemia P388 transplanted into mouse. Namely, Example 2 shows that a combination administration of Compound 2 with CDDP (cisplatin) in disease-model mice gives significantly higher T/C (%) than single administration of each drug, where Applicants have demonstrated significantly higher T/C (%) values. Such improved values were observed when administering the compounds sequentially or simultaneously and across different relative amounts. (See e.g. pages 20-23 and the results of Table 1.) Moreover, Applicants have reported that specific dosage amounts can depend upon for example, age, sexuality, severity of disease, and dosage of CDDP. Consequently, claim 1 is patentable for at least the foregoing reasons.

In view of the above amendments and remarks, Applicants respectfully request favorable reconsideration of this application in the form of a Notice of Allowance. If any questions arise regarding this communication, the Examiner is invited to contact Applicants' representative listed below.

Respectfully submitted,

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. Box 2902
Minneapolis, MN 55402-0902
(612) 455-3800

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By: _____
Douglas P. Mueller
Reg. No. 30,300
DPM/BAW/mmz